DEPARTMENT OF HEALTH & HUMAN SERVICES





Food and Drug Administration Washington, DC 20204

OCT 1 0 1997

Alexis Gambetta Chief Executive Officer HealthMark 4700 East Iliff Avenue Denver, Colorado 80222-6025

0777 '97 DEC 16 P1:39

Dear Ms. Gambetta:

This is in response to your letter of October 1, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that HealthMark is making a number of claims for "Herbal Dietary Supplement Standardized Potency Echinacea." These claims, among other things, state that the product is for "Increased Natural Resistance to Seasonal health Problems" and is "...an especially popular dietary supplement during the cold and flue season and is often recommended by health care specialists."

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product, taken together, suggest that it is intended to treat or prevent a disease, namely cold and flu. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also contained a label for a Multiple Vitamin/Mineral with Iron dietary supplement, which contains 7.5 milligrams (mg) iron per recommended dosage. We would like to note that in the January 15, 1997 Federal Register (62 FR 2218; enclosed), FDA published a final regulation requiring a label warning statement on products taken in solid oral dosage form to supplement the dietary intake of iron. Your product label does not contain the label warning statement required by 21 CFR 101.17. A dietary supplement in solid oral dosage form that contains added iron, that enters interstate commerce after the effective date for implementation of this regulation (July 15, 1997), and that does not bear the required warning statement on its label or in its labeling, is misbranded under sections 403(a)(1) and 201(n) of the act.

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Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200 FDA, Denver District Office, Office of Compliance, HFR-SW240



October 1, 19970 7 7 8



Office of Special Nutritionals Center for Food Safety and Applied Nutrition Food and Drug Administration "C" Street SW (HFS-455) Washington, D.C. 20204

To Whom It May Concern:

Enclosed please find labels for vitamins that HealthMark is marketing. As per FDA guidelines, I am informing you within 30 days after first marketing a statement of nutritional support.

Should you need any further information, please do not hesitate to contact us.

Sincerely,

Alexis Gambetta

Chief Executive Officer

/ag

cc: Dr. Robert Gleser - HealthMark

Dr. Mitchell Gershten - HealthMark

Dr. Wayne Peters - HealthMark

Health Mark

4700 East Hiff Avenue Denver, CO 80222-6025 (303) 584-8900 Fax: (303) 584-0525 505

RECOMMENDATIONS
As a dietary supplement for adults, take one capsule daily as recommended by your health care practitioner or nutritional counselor.

Each Cassula Contains

Each Capsule Contai	112:		
NUTRIENT SOURCE	POTEN	CY '	%USRDA*
Vitamin A (acetate, beta carotene)	7,500	IU	150
Vitamin B1 (thiamine HCl)	5.5	mg	367
Vitamin B2 (riboflavin)	5	mg	200
Vilamin 83 (niacin & Inositol niacinate)	30	mg	150
Vilamin B5 (calcium pantothenate)	35	mg	350
Vilamin B6 (pyrodoxine Hcl)	10	mg	500
Vitamin B12 (cyanocobalamin)	30	me	500
Falic Acid	200	meg	50
Bilotin	100	mc	3.3
Vitamin C (ascorbic acid)	250	mg	417
Vitamin D3	100	IU	25
Vitamin E (acetate)	100	1U	333
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Distributed by: HealthMark Centers, L.L.C. A Center for Integrated Healings 4700 East Iliff Avenue

Denver, Colorado, USA 80222

Q.C.#

(305) 584-8900

EXPIRATION



Dietary Supplement

MULTIPLE VITAMIN/MINERAL with IRON

60 Capsules (775 mg.)





Molyhdenum (aspartate) 30 mCg
Recommended Daily Allowance
No USRDA espalbished for this nutrient. In a base of natural
storients including vegetable phytonutrients.
Storie in a coul, dry place sway from sunlight and monuter
On Not Consume If You Are Perganni, Leataing, On Medication.
Have A Medical Condition Or Under A Physicians Care Writhout
Irist Consulting Your Doctor. Keep Out Of Reach Of Children.

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RECOMMENDATIONS:

As a dietary supplement for adults, take one or two capsules twice daily or as recommended by your health care practitioner. For best results, use for no more than 2 - 10 days.

CONTENTS:

Echinacea concentrated root extract (angustifolia and purpurea) standardized to 4% tall phenolic compounds, natural excipients, ore in a cool, dry place away from sunlight and moisture.

Do not consume if you are pregnant, lactating, on medication, have a medical condition or under a shysician's care without first consulting your doctor.

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Q.C.#

EXPIRATION:

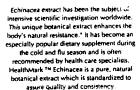


Herbal Dietary Supplement Standardized Potency

(Echinacea purpurea and angustilolia)
Increased Natural Resistance to Seasona Frealth Problems*

60 Capsules (130 mg. each)

JHealth Mark



*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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